Department of Veterans Affairs **VHA DIRECTIVE 2002-075**
Veterans Health Administration
Washington, DC 20420 **November 20, 2002**

CONTROL OF HAZARDOUS MATERIALS IN VA RESEARCH LABORATORIES

1. **PURPOSE:** This Veterans Health Administration (VHA) Directive establishes policy and guidance related to the prevention and/or detection of terrorist events occurring in or originating from Department of Veterans Affairs (VA) research laboratories.

NOTE: *The policies contained in this Directive apply to all Research and Development (R&D) laboratories located within VA medical centers or other VA facilities, including leased space, and to space within a VA facility leased to a private entity. VA laboratories located in approved off-site facilities such as affiliate universities are expected to comply with all Federal laws and regulations regarding security of research laboratory facilities.*

2. **BACKGROUND**

a. The scope of this Directive includes the physical and organizational controls surrounding the storage and use of hazardous agents. Applicable physical security requirements must be applied to all research areas as described in VA Handbook 0730, Appendix B, "Physical Security Requirements and Options."

b. The availability of human pathogens, their products, chemicals, gases, radioactive materials, and/or radioactive sources for VA research is essential for advancing medical knowledge relevant to improving the health care needs of the veteran population. In the past decade, biological and chemical terrorist events in the United States and in other countries have become a reality. It is the responsibility of the VA Office of Research and Development (ORD) to develop policies to prevent illegal entry into research areas and the improper use and/or theft of hazardous materials. The protection of VA personnel, patients, visitors, and the surrounding community from terrorist events demands stringent controls on the use of hazardous agents capable of being used as weapons of mass destruction.

c. The VA R&D program operates its laboratories in compliance with policies, statutes, and regulations of appropriate Federal agencies including VA, the Occupational Safety and Health Administration (OSHA), the Environmental Protection agency (EPA), the Nuclear Regulatory Commission (NRC), the Department of Transportation (DOT), and any applicable state or local regulations. All applicable guidelines issued by the Department of Health and Human Services (HHS), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) must be followed as documented in VHA Handbook 1200.8, "Safety of Personnel Engaged in Research." This handbook specifically addresses security policies that are distinct from those relating to laboratory safety, but that may overlap with those policies.
NOTE: *Policies, procedures, and responsibilities for laboratory security, personnel identification and training, inventory controls, and the interactions with other facility personnel such as security and law enforcement personnel are addressed in this Directive.*

THIS VHA DIRECTIVE EXPIRES NOVEMBER 30, 2007

d. **Definitions.** For purposes of this Directive, the following definitions apply.

(1) **Terrorist Event.** A terrorist event is the unauthorized removal or theft of hazardous agents capable of being used as weapons of mass destruction from VA research laboratories, or other VA assigned space (including off-site space) and/or the unlawful use of such hazardous agents. It specifically encompasses the illicit and unauthorized use of VA laboratory facilities (including equipment, supplies, computers, faxes, phones, etc.) for the production, purification, or dissemination of any hazardous agent. The term also refers to the illegal transfer of agents into or out of VA research laboratories and other research space such as animal care facilities, storage areas, offices, etc.

(2) **Hazardous Agent.** A hazardous agent is a biological material including, but not limited to, the CDC list of Select Agents and products of such a biological material, i.e., toxins. For purposes of this Directive, the term also includes highly toxic chemicals or gases that have the potential for being used as weapons of mass destruction, as well as radioactive materials and/or radioactive sources. Refer to Attachment A for a list of biological and chemical agents and a description of radioactive materials and/or radiation sources recognized as meeting this classification.

(3) **Select Agent.** A Select Agent is one of a group of agents (viruses, bacteria, rickettsiae, fungi, toxins, and recombinant deoxyribonucleic acid (DNA) designated by the CDC as requiring registration with the CDC Laboratory Registration Program. The regulation of Select Agents is codified in Title 42 Code of Federal Regulations (CFR) Part 72, Additional Requirements for Facilities Transferring or Receiving Select Agents. All Select Agents are included in the list of hazardous agents listed in Attachment A. For purposes of this Directive, Select Agents and Hazardous Agents are synonymous, and are to be handled at the same level of security.

(4) **Weapons of Mass Destruction.** Weapons of mass destruction include any of the classes of hazardous agents as defined in paragraph 2.d(2) and identified in Attachment A, or combinations of these agents that are capable of inflicting morbidity and mortality on a widespread basis.

(5) **Laboratories.** Laboratories are research laboratories under the control of VA ORD. In the context of this VHA Directive, the laboratory director is the VA investigator responsible for a particular laboratory.

NOTE: *Laboratories include: (1) VA laboratories located within VA medical centers or other VA facilities, including leased space;(2) VA laboratories located in approved off-site facilities such as affiliate universities; and (3) laboratories within the VA medical center in space that is leased to a private entity.*

(6) **Sensitive Materials.** Sensitive materials include, but are not limited to, any hazardous agents as defined in paragraph 2.d(2) and identified in Attachment A, as well as research equipment and/or supplies used to store, test, destroy or otherwise handle hazardous agents, and laboratory notebooks or other written or computerized records documenting possession of and/or research using hazardous agents.

(7) **USA Patriot Act.** The USA Patriot Act, Public Law 107-56, October 26, 2001, was passed by Congress in response to the terrorist attacks of September 11, 2001. The purpose of the Act is to unite and strengthen America by providing appropriate tools to intercept and obstruct terrorist acts. The law includes provisions to deter and punish terrorist acts, enhance law enforcement investigatory tools, and other purposes such as aid to victims of terrorism. The Act also prohibits certain restricted persons from possessing biological agents or toxins that are identified as select agents in Title 42 CFR Part 72. This provision of the Act, codified at Title 18 United States Code (U.S.C.) § 175b, defines a "restricted person" as including, among others, an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country that has repeatedly provided support for acts of international terrorism. ***NOTE:*** *The Secretary of State makes such determinations; to date, identified countries include Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria.*

e. **Penalties.** Failure to conform to the requirements and standards of this Directive may result in immediate withdrawal of VA research funding and/or suspension of the research program. Individuals who knowingly fail to follow the provisions of this Directive are subject to disciplinary action proportionate to the severity of the violation, up to and including termination of VA employment.

3. POLICY: It is VHA policy that each health care facility must ensure VA research laboratory and inventory security of hazardous materials.

4. ACTION

a. **Chief Research and Development Officer (CRADO), VHA Central Office.** The CRADO is responsible for the overall research laboratory antiterrorism policy, planning and coordination of system wide plans to prevent terrorist events from occurring in VA research laboratories, and maintaining the highest level of laboratory and inventory security.

b. **Veterans Integrated Service Network (VISN) Directors**. VISN Directors are responsible for ensuring:

(1) That each medical facility under their jurisdiction is in compliance with current policies and guidelines relating to the prevention of terrorist events.

(2) The physical security of medical centers, research laboratories, and other specialized containment areas including biosafety level (BSL)-3 laboratories and animal care facilities throughout their respective VISNs.

c. **Facility Directors.** The Director, or Chief Executive Officer (CEO), of each health care facility is responsible for:

(1) Ensuring that adequate staffing and resources are available to maintain the security of the facility, including research laboratories.

(2) Ensuring that all the specifications for personnel and facility security and law enforcement contained in VA Handbook 0710, "Personnel and National Information Security," and VA Directive and Handbook 0730, "Security and Law Enforcement," are adhered to by facility staff, patients, visitors, and guests.

(3) Ensuring that the following mandated policies are published as facility policy.

(a) Laboratory Access. Access to research laboratories must be controlled and limited to authorized individuals. No research laboratories will be open to the public. All laboratory areas, including animal housing areas and storage areas, must include a state-of-the-art keycard or equivalent system that generates permanent, dated records with identification of persons entering the area and times of entry and exit. Issues that must be considered in implementing this policy include:

1. Access control must be on a 24-hour, 7-days per week schedule (i.e., must include holidays and weekends).

2. An intrusion alarm system must be present and either connected to, or otherwise monitored by, the facility VA Police Service.

3. The Associate Chief of Staff for Research and Development (ACOS for R&D), or other research personnel designated by the ACOS for R&D, must conduct and document a review of access records on a weekly basis. A written record of each review must be retained by the local research office in accordance with guidelines established by the Office of Security and Law Enforcement (07). Irregularities identified during a review or in the course of daily activities must be immediately reported to VA Police Service, the medical center Director, the research office, and other appropriate personnel identified by the facility.

4. A record of keycard assignments must be current at all times. Personnel, including WOC appointees and contract employees as well as non-citizens, leaving VA employment or no longer working in the research laboratory must adhere to full clearance and checkout procedures. This includes turning in all identifications, passes, keys, keycards, and other access items. Returned keycards must be deactivated within 24 hours. Appropriate facility staff must immediately update records to reflect the turn-in of all access items; documentation must include the date and reason for termination.

NOTE: *Restrictions and guidelines for laboratory access must ensure adequate and sufficient access for the health and safety staff and for authorized inspectors from regulatory agencies and VHA oversight offices. Laboratory access restrictions must not preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.*

5. Research laboratories not used to house or test hazardous agents (as defined herein and identified in Attachment A) may be exempted from some physical and personnel security requirements. The extent to which an exemption will be granted will be based on security risk

and procedures for specific laboratory areas. In order to receive such an exemption, a waiver request from the medical center Director must be submitted to and approved by the CRADO, VHA Central Office. Under no circumstances will a waiver be granted for a Biosafety Level (BSL)-3 or BSL-4 laboratory or a BSL-2 laboratory used to house and/or test hazardous and/or select agents. Procedures for submitting waiver requests are contained in Attachment B.

(b) Personnel. All personnel must obtain formal authorization prior to beginning work in laboratory areas.

1. Facility management, VA Police Service, human resources, the research office, the facility safety manager, and the Radiation Safety Officer and/or industrial hygienist must:

a. Coordinate efforts to identify individuals currently granted access to laboratories housing hazardous agents, to evaluate the appropriateness of their access into these areas.

b. Review and approve, as appropriate, future requests for access into these areas. Issues that must be considered in implementing this policy include:

2. Students, fellows, residents, visiting scientists, and others to be granted access must be included, and their access needs to be limited to hours when authorized VA employees are present.

3. VA must review applications from non-United States citizens for their current residency status in the United States prior to employment or granting access to laboratory areas. The Human Resources Service is responsible for reviewing, verifying, and tracking citizenship and visa status. Follow-up with appropriate external agencies such as the Immigration and Naturalization Service may be necessary to clarify or validate a non-citizen's credentials. The Office of Security and Law Enforcement is responsible for conducting personnel security background checks for controlled area access. ***NOTE:*** *Careful attention to these procedures is required to ensure that inappropriate or illegal non-citizens are not permitted in VA facilities. Discrepancies must be reported to the local Federal Marshal through the VA Police Service.*

4. An alien (other than an alien lawfully admitted for permanent residence) who is a national of a country determined by the Secretary of State to have repeatedly provided support for acts of international terrorism may not be granted access to any sensitive areas in which select agents (as defined in Title 42 CFR Part 72) may be present. Individuals meeting any other criteria for identification as a "restricted person" are similarly prohibited from accessing sensitive areas and/or possessing select agents (18 U.S.C. §175b) (see subpar. 2d(7)).

5. Laboratory directors must submit a written request to the facility R&D Committee to obtain permission for individuals to access restricted areas in which hazardous agents are used.

6. A request for access to the research laboratories must be submitted by the laboratory director and approved by the R&D Committee prior to new personnel beginning work in the laboratory area. Level of security or access restrictions must be clearly noted, i.e., individuals permitted to access storage areas, animal care areas, or special containment facilities such as BSL-3 facilities.

7. The request must specify the individual's legal address, employment status, basis for which access is required, and a description of the sensitive material in the laboratory area in which the individual will work.

8. The appropriate facility managers must be notified of the approval or disapproval of requests for laboratory access.

9. The status of personnel granted access to laboratories must be reviewed at least semi-annually, or as needed, by VA laboratory directors and the research office. The R&D Committee must be formally notified following the review of the individuals requiring continued access to sensitive laboratory areas. Explanation needs to be provided to the R&D Committee sufficient to allow an informed concurrence on the continued access. The R&D Committee must also be notified of individuals who no longer require access to laboratory areas.

10. Personnel are to enter laboratory areas only when required to perform their duties and responsibilities.

11. Any changes in personnel status must immediately be reported to VA Police Service, the research office, and a facility designee. Individuals leaving VA employment or no longer working in the research laboratory are expected to comply with the procedures described in subparagraph 4c(3)(a)4. In the event an individual with access to a laboratory inexplicably disappears, is suspected to have violated procedures, or committed a security breach, VA Police Service and other security officials including the Office of the Inspector General must be notified immediately. ***NOTE:*** *Law enforcement officials are to take necessary steps to treat the areas affected as potential crime scenes.*

NOTE: *Restrictions and guidelines for personnel must ensure adequate and sufficient access for the health and safety staff and for authorized inspectors from regulatory agencies and VHA oversight offices. Personnel procedures must not preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.*

(c) Security Procedures. Procedures must be developed and implemented to ensure that only authorized individuals have access to research laboratories. Issues that must be considered in implementing this policy include:

1. All medical center personnel (full-time, part-time, WOC), and others engaged in research on a short-term basis such as students, fellows, residents, and visiting scientists, must wear photo identification badges at all times. Photo identification badges should contain clearly visible valid expiration dates.

2. All visitors to secure laboratory areas, including service, maintenance, and safety personnel and commercial vendors, must sign in and out specifying their name, affiliation, purpose for visiting, and times of arrival and departure. A valid personal identification containing a photograph of the individual must be provided prior to being admitted to laboratory

areas. Badges designated by the facility for visitors must be issued by VA Police Service or other appropriate security personnel. Visitor badges must be worn at all times, be readily distinguishable from VA employee badges, and be surrendered upon leaving the medical center. Visitor access must be limited to hours when authorized VA employees are present.

3. Visitors must be accompanied at all times by a VA employee authorized to enter the laboratory area. This employee is responsible for the visitor's activities and conduct, and for ensuring that the escorted visitor exits the area at the appropriate time.

4. Vendors must be restricted from all laboratory areas unless Acquisition and Materiel Management Service (A&MM) has approved an appointment and VA Police Service has authorized the vendor to enter VA premises. A mechanism to obtain these approvals and notify the research office that a vendor is authorized to enter a laboratory area must be developed and implemented at the local level.

5. Upon arrival, all vendors must comply with any local requirements for clearance from VA Police Service and A&MM prior to being admitted to any research laboratory areas.

6. Delivery companies must certify that their personnel are bonded and possess photo identification badges that clearly identify their company affiliation. Companies that transact business with VA and whose employees require access to VA property must provide documentation of U.S. citizenship or an authorized and appropriate non-citizen status. ***NOTE:*** *The medical center is to request results of completed background checks, including for any past criminal activity, for vendors' employees who may be permitted to be near or escorted into a secure laboratory or other sensitive area.*

NOTE: *Restrictions and guidelines for security procedures must ensure adequate and sufficient access for the health and safety staff and for authorized inspectors from regulatory agencies and VHA oversight offices. Security procedures must not preclude or interfere with employee or worker opportunity to report safety concerns or to participate in other protected activities under Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.*

(d) Security Standards. Physical security of all areas of the facility housing hazardous agents must meet appropriate standards determined by the Office of Security and Law Enforcement, regulatory agencies, and/or cognizant VA oversight offices. Facility security standards must be reviewed on an annual basis. The ACOS for R&D is responsible for informing the Office of Safety and Law Enforcement of any changes in research affecting a facility security rating.

(e) Emergency Preparedness. Each facility with research laboratories must develop and implement an emergency preparedness plan. The plan must include all elements required by OSHA in Title 29 CFR 1910.120, Hazardous Waste Operations and Emergency Response, VHA Emergency Management Program Guidebook, and VHA Handbook 1200.8, Attachment F. It must address:

1. Actions to be taken in the event of an intentional release of chemical or biological materials to the atmosphere, wastewater system, or immediate environment.

2. Emergency evacuation plans for all facilities with consideration of the impact on the evacuation route of agents and materials used in the laboratory.

3. And other issues to include facility policy and procedures for disaster planning, security surveys, and security training. ***NOTE:*** *The policy must be updated annually to include provisions for response to terrorist activities.* The policy and plan must include:

a. A provision for providing a listing of all hazardous materials in research laboratories to the Local Emergency Planning Committee and participating with their emergency drills and activities.

b. A Spill Prevention Control and Counter Measures (SPCC) plan specifically addressing research laboratories.

c. A description of the facility response to an intrusion alert including provisions for non-standard duty hours, nights, and holidays.

d. A facility designee who can be contacted at all times.

e. A designee from the Research Service.

f. A response cascade with contact names, phone numbers, and other contact information listed.

g. Procedures for ensuring protection of sensitive materials and equipment during an illegal intrusion or activity. ***NOTE:*** *These procedures are to include the role of police and research personnel.*

h. Lock down procedures of the facility to

(1) Protect patients, visitors, and personnel; and

(2) Prevent theft or destruction of sensitive materials or equipment.

i. Emergency preparedness drills for response to terrorist activities.

j. Initial and annual vulnerability assessments of all research facilities by a multidisciplinary team consisting of local research personnel, VA Police Service, the facility Safety Officer and Safety Manager, Radiation Safety Officer, and/or Industrial Hygienist. This assessment is to identify high-risk areas, sensitive materials, and physical security issues.

(1) Initial assessments need to include: access security (doors, windows, wall openings, ceilings, partitions); utility system security (electricity, ventilation, water, wastewater); and information security.

(2) The results of the assessment must be provided to the local Subcommittee on Research Safety (SRS) and the medical center Director.

(3) Training of facility personnel must reflect the assessment by addressing all aspects of responding to intrusions and/or terrorist events including: security awareness training, and emergency procedures to detect and safely respond to unauthorized individual(s) in research laboratory areas.

(f) Inventory Controls. Each facility with research laboratories must develop inventory controls for hazardous agents including biological, chemical, gaseous materials, and radioactive materials and/or radioactive sources. Normally the Radiation Safety Officer maintains accountability for radioactive materials and/or radioactive sources. A current, complete list of hazardous chemicals, as defined by OSHA and EPA, must be maintained for each VA research laboratory. Chemical inventories must be updated at the time a new chemical is introduced into the laboratory. A hazard assessment will be conducted prior to introduction to determine the impact on the facility's emergency preparedness program. In accordance with VHA Handbook 1200.8, the facility Safety Officer must review and approve chemical inventories. These inventories may be conducted by laboratory personnel on a daily, weekly, or monthly basis, but the review by the Safety Officer must be done on at least a semi-annual basis. Issues that must be considered in implementing this policy include:

1. Procurement actions must be conducted according to the Federal Acquisition Regulation (FAR) and the Veterans Administration Acquisition Regulation (VAAR). The independent purchase, possession, receipt, or use of hazardous laboratory materials without appropriate authorization is prohibited.

2. Inventory transfers must be in compliance with DOT, OSHA, NRC, and CDC regulations. Transfer of any hazardous materials, including but not limited to those specifically identified as CDC select agents, must be documented as to the identity of the receiver of said materials, where it is being transferred, and the date of the transfer. If a Select Agent is involved in the transfer, the procedures described in subparagraph 4c(3)(f)7a through subparagraph 4c(3)(f)7e must be followed. All transfers must be reported to the SRS prior to the transfer. Transfers of radioactive materials and/or radioactive sources will be reported to the ACOS for R&D prior to transfer.

3. Security of hazardous agents in leased space or in approved off-site space must be ensured. New off-site space must be reviewed and approved by the Office of Security and Law Enforcement. The VA investigator is responsible for ensuring inventory is reported and for informing the ACOS for R&D regarding inventory changes which may affect the security rating.

4. Procedures for delivery and handling of highly sensitive materials must be adhered to and must be documented. Packages containing specimens, bacterial or virus isolates, or toxins are to be opened in a safety cabinet or other appropriate containment device.

5. Hazardous materials not currently in use on approved protocols and for which there are no immediate plans for use must be destroyed or disposed of by other method approved in applicable regulations. Procedures for implementing this destruction at the local level must be established and implemented. Prior to the destruction of hazardous materials capable of being used as weapons of mass destruction, permission must be obtained from the VISN Safety Office through the medical center Director, the facility safety manager, the ACOS for R&D, the R&D Committee, and the SRS.

6. Destruction of highly sensitive materials must be witnessed and documented by a scientist, or other professionally qualified individual, not directly associated with the investigator's laboratory and having sufficient skills and knowledge to verify that the sensitive materials are destroyed or inactivated. The process must be carried out to ensure that the material cannot be cultured or a part of it removed without knowledge of the witness. The documentation must be provided to the facility Safety Officer and the R&D Committee. The documentation must include the date and means of destruction or inactivation, and must be signed by the VA investigator, by the personnel actually destroying the material, by one witness not directly associated with the investigator's laboratory, and by at least one person from the local research office (i.e., the ACOS for R&D, or designee). Following destruction of the material, the signed and dated documentation must be forwarded to the local and VISN Safety Offices, as well as the local research office.

7. Registration with the CDC Laboratory Registration Program must occur before select agents specified in Title 42 CFR 72.6 are used in research protocols or otherwise stored in a laboratory. The following procedure for applying for a CDC laboratory registration number must be followed:

a. The ACOS for R&D must submit a letter of intent on behalf of the investigator to CRADO through the facility Chief of Staff, medical center Director, and VISN Director, prior to requesting a select agent laboratory registration number from the CDC.

b. The letter of intent must contain a detailed justification for the use of select agents in a VA research laboratory. It must also include a description of measures ensuring physical security of the select agents and a list of all personnel who will be granted access to the select agent.

c. The completed CDC application must be reviewed and approved by the local SRS, R&D Committee, Chief of Staff, medical center Director, and VISN Director.

d. Following local approval, but prior to submission to the CDC, the application form must be reviewed and approved by CRADO, or designee at VHA Central Office.

e. Following receipt of a CDC laboratory registration number, a site inspection of the research laboratory or laboratories involved must be scheduled with the ORD prior to acquisition and use of the select agent(s). No select agent may be brought on-site prior to this inspection. Violation of this requirement may result in suspension of the project and withholding of the facility's research funds.

8. All facilities must comply with requirements to register all Select Agents stored at, used by, and/or transferred to/from the facility (see reference in para 5.f).

9. Freezers, refrigerators, cabinets, and other containers where stocks of biological agents, hazardous chemicals, or radioactive materials are stored must be locked when they are not in direct view of workers (e.g., when located in unattended storage areas).

d. **ACOS for R&D.** The ACOS for R&D is responsible for:

(1) All activities in the Research Service including the implementation of all requirements set forth in this Directive.

(2) Appointing, or serving as, the designated research staff interacting with appropriate facility security personnel, health and safety staff, and oversight committees (e.g., Radiation Safety Committee).

(3) Ensuring the medical center Director, CEO, or designee, remains informed of all activities involving sensitive materials. ***NOTE:*** *Changes in facility security procedures must be made known to the research service expeditiously.*

(4) Ensuring that all non-VA persons working in research areas, or in VA-space leased to another institution, conform to all VA standards for security as described in this Directive.

(5) Completing the annual vulnerability assessment of research areas, and for informing appropriate facility personnel and CRADO of the assessment results.

(6) Informing the Office of Safety and Law Enforcement of any changes in research affecting the facility security rating.

e. **Research and Development (R&D) Committee.** The R&D Committee is responsible for:

(1) Controlling access to laboratory areas housing hazardous agents by:

a. Reviewing and approving requests for individuals' access submitted by laboratory directors.

b. Reviewing the status of personnel granted access to laboratories at least semi-annually (see subparagraphs. 4c(3)(b)5. through 4c(3)(b)10.).

(2) Reviewing and approving requests to destroy hazardous materials that could be used as weapons of mass destruction, and

(3) Reviewing and approving requests for a CDC laboratory registration number to document the receipt, transfer, or use of select agents.

f. **VA Investigator.** The VA investigator is responsible for:

(1) Identifying the level of security access required of research laboratory staff being considered for employment or work within the investigator's research laboratory. ***NOTE:*** *This includes WOC appointees, fellows, residents, and visiting scientists.*

(2) Educating the research laboratory staff specific to the hazardous nature of materials they will be using and the security precautions to be followed in handling, transferring or destroying such materials.

(3) Regularly reviewing and accounting for inventory of hazardous agents. ***NOTE:*** *The review period may be daily, weekly, and monthly according to the nature of the substance, but may not exceed 6 months.*

(4) Forwarding a copy of the inventory to the facility Safety Officer or Radiation Safety Officer as appropriate to the nature of the materials on, at least, an annual basis.

5. REFERENCES

a. Title 18 U.S.C. § 175b.

b. Title 29 CFR 1910.120.

c. Title 42 CFR Part 72.

d. VHA Handbook 1200.8, "Safety of Personnel Engaged in Research," issued June 7, 2002.

e. VA Directive and Handbook 0730, "Security and Law Enforcement," issued August 11, 2000.

f. Public Law 107-188, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

g. Title 10 CFR Parts 19 and 30, the Civil Service Reform Act of 1978, and the Whistleblower Protection Act of 1989.

6. FOLLOW-UP RESPONSIBILITY: The VHA Office of Research and Development (12) is responsible for the contents of this Directive. Questions may be referred to ORD at (202) 565-8440, or by facsimile at (202) 565-8738.

7. RESCISSIONS: None. This VHA Directive expires November 30, 2007.

Robert H. Roswell, M.D.
Under Secretary for Health

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ATTACHMENT A

HAZARDOUS BIOLOGICAL AND CHEMICAL AGENTS

1. The Centers for Disease Control and Prevention (CDC) has identified certain biological, chemical and radioactive materials or agents as having potential for use as weapons of mass destruction. Improper use and/or containment of these materials or agents pose a risk to national security because of their: 1) ease of dissemination or transmittal between individuals; 2) potential for high mortality rates and major public health impact; 3) potential for causing public panic and social disruption; and 4) risk for public health preparedness.

2. Storage and/or use of these materials or agents in any quantity in a Department of Veterans Affairs (VA) research laboratory requires special consideration for physical security, personnel access, inventory control, and emergency preparedness.

a. Biological Agents

Abrin
Aflatoxins
Bacillus anthracis (anthrax)
Botulinum toxin
Brucella abortus, B. melitensis, B. suis
Burkholderia (Pseudomonas) mallei
Burkholderia (Pseudomonas) Pseudomallei
Closiridium botulinum
Clostridium perfringens epsilon toxin
Coccidioides immitis
Conotoxins
Coxiella bumetii
Crimean-Congo hemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis Virus
Ebola Virus
Equine Morbillivirus
Francisella tularensis
Lassa Fever Virus
Marburg Virus
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Rift Valley Fever Virus
Saxitoxin
Shigatoxin
South American Hemorrhagic Fever Viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
Staphylococcal enterotoxins
T-2 Toxin
Tetrodotoxin
Tick-borne Encephalitis Complex Viruses

Variola Major Virus (Smallpox Virus)
Venezuelan Equine Encephalitis Virus
Viruses causing Hantavirus Pulmonary Syndrome
Yellow Fever Virus
Yerseinia pestis

b. Chemical Agents

3-quinuclidinyl benzilate (BZ)
Chlorine gas
Cyanogen chloride (CK)
Cyclosarin (GF)
Diphosgene (DP)
Hydrogen cyanide (AC)
Lewisite (L) – note there are 3 individuals chemicals included in this category
Lysergic acid diethylamide (LSD)
Nitrogen mustard (HN-1, HN-2, or HN-3)
Phosgene (CG) – also known as carbonyl chloride
Phosgene oxime (CX)
Sarin (GB)
Soman (GD)
Sulfur mustard (H, or HD, or HT), also called mustard gas or mustard agents
Tabun (GA)
VX (VX is both the name and symbol)

c. Radioactive Materials and/or Radiation Sources

(1) The special considerations required for radioactive materials and/or radiation sources should be based on the specific radionuclide, the half-life, and the quantity present. For a "radiation high-risk" situation, more restrictive security measures should be followed. For a "radiation low-risk" situation, basic security measures should be followed.

(2) "Radiation high-risk" is a single location or room where the total activity of a single radionuclide with a half-life of more than 3 days is greater than one Curie and the radionuclide is received, store, or used. "Radiation low-risk" is any location other than a "radiation high-risk" location and where radioactive materials and/or radiation sources are received, stored, or used.

3. As additional agents or materials are identified by the CDC, those agents or materials will be considered by VA as hazardous agents, and will be subject to the same security requirements as those agents or materials identified in paragraph 2 above.

ATTACHMENT B

INSTRUCTIONS FOR PREPARATION AND SUBMISSION OF REQUESTS FOR EXEMPTION TO SPECIAL SECURITY CONSIDERATIONS FOR VA RESEARCH LABORATORIES

1. Format. Applications should consist of single-spaced typed pages. Use only letter-quality print. The font size should be at least eleven point with no more than fifteen characters per inch and no more than six lines per inch.

2. **Content.** Each application should consist of the following materials:

a. A cover sheet listing the following information in the order specified:

(1) Laboratory Security Waiver Request.

(2) VA medical center name and address.

(3) Location of laboratory(ies) for which waiver is requested, including:

(a) Lab location (VA medical center, VA leased space, or off-site).

(b) 2) building and room number.

(4) VA Laboratory Director (name and degree of investigator).

(5) Does the facility have a Biosafety Level (BSL) 3 laboratory? If so, identify the BSL-3 location. Describe the proximity of the BSL-3 to the laboratory for which the waiver is requested.

(6) Are any hazardous agents (as identified in Attachment A) housed in any laboratory within the facility? If so, identify the agent(s) or material(s), investigator(s) using the agent(s) or material(s), and identify laboratory location and proximity to the laboratory for which the waiver is requested.

(7) Name, title, and signature of the Associate Chief of Staff for Research and Development.

(8) The following statement followed by the name, title, and signature of the medical center Director: I certify that the information contained in this request for exemption to special security considerations for VA research laboratories is accurate and complete.

b. A narrative describing the following:

(1) **Brief description of research conducted in the laboratory.** Include general overview, specific biological or chemical agents or radioactive materials and/or radiation sources used.

(2) **Discussion of security accommodations and procedures for the overall VA medical center or other facility.** Include a description of access control procedures, screening of personnel, and emergency preparedness**.**

(3) **Discussion of proximity of the laboratory area(s) in relation to patient care facilities.** What security measures are in place to ensure that wandering patients and/or visitors do not inadvertently enter laboratory areas? Would increased laboratory security measures adversely affect patient care?

(4) **Discussion of any specialized security accommodations and procedures for the laboratories within the facility that house hazardous agents (as identified in Attachment A).** Include a description of special access control procedures, screening of personnel, and emergency preparedness**.** If no hazardous agents (as identified in Attachment A) are used at the facility, so state.

(5) **Discussion of the financial, staffing, and other logistical ramifications for the facility if the request for waiver is denied.**

c. A floor plan on 8.5 x 11 inch paper with the location of the laboratory(ies) for which an exemption is requested.

3. **Due Dates**. Requests may be submitted at any time. VA medical centers are encouraged to submit consolidated requests rather than separate requests for individual laboratories.

4. **Mailing Addresses.** Applications are to be mailed to the address listed below:

Department of Veterans Affairs
Office of Research and Development (12)
810 Vermont Ave, NW
Washington, DC 20420